MAR 15 2012

510(k) Summary
CareFusion Nicolet EDX with Viking Software

[A summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92]

1. Submitter / 510(k) Holder

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2. Device Name

Proprietary name	CareFusion Nicolet EDX with Viking Software
Common name	Diagnostic Electromyograph
Device Class	Class II
Classification name	Evoked Response Electrical Stimulator Diagnostic Electromyograph Nerve Conduction Velocity Measurement Device Non-normalizing Quantitative Electroencephalograph Software Evoked Response Auditory Stimulator Evoked Response Photic Stimulator Evoked Response Mechanical Stimulator
Product Code, Regulation	GWF 21 CFR §882.1870 IKN 21 CFR §890.1375 JXE 21 CFR §882.1550 OLT 21 CFR §882.1400 GWJ 21 CRF §882.1900 GWE 21 CFR §882.1890 GZP 21 CFR §882.1880

3. Predicate Devices

510(K) Number	Device Name
K890495	CareFusion Viking II System
K965065	CareFusion Synergy Mobile System
K984052	CareFusion Synergy IOM System
K991054	CareFusion Bravo Multi-Modality System

K102610	TeleEMG Focus EMG
K924723	Cadwell Sierra Wave System
K010590	Nihon Kohden Micro System

4. Device Description

The CareFusion Nicolet EDX system with Viking Software (Viking EDX) is designed for the acquisition, display, analysis, reporting, and management of electrophysiological information from the human nervous and muscular systems. The system is designed to perform nerve conduction studies (NCS), needle electromyography (EMG) testing, evoked potential (EP) testing, and intra-operative monitoring (IOM). The system can also perform multi-modality recording through Multi-mode programs (MMP). Viking EDX provides a variety of tests spanning the various modalities.

The Viking EDX consists of the following major components:

- Nicolet EDX console base unit;
- Viking control panel;
- Nicolet amplifier (there are two types available: 2 channel (AT2) with two non-switched amplifier channels and an 8 channel (AT2 + 6) amplifier with two non-switched and six switched amplifier channels;
- Desktop or laptop computer with a keyboard and mouse;
- Display monitor; and
- Viking Software

The Viking EDX optional accessories/components consists of the following:

- Nicolet HB6 or HB7 Head Box
- Stimulator probes (RS 10 probe, WR 50 Probe, S403 probe)
- SP1/SP2 electrical stimulator switching units
- Footswitches (single and triple)
- LED goggles
- Patient response button
- Photic strobe
- Headphones or other auditory transducers
- Cart
- Isolation transformer
- Printer

Description of Major Components

Nicolet EDX Console Base:
The console base is an AC mains powered electrical device that houses the core Nicolet EDX hardware, and provides interconnection capability with the rest of the Nicolet EDX hardware and PC. The PC contains the software.

Viking Control Panel:
The control panel along with the mouse is the primary user interface for the Nicolet EDX system. The control panel contains a variety of controls that allow the user to access and use the Nicolet EDX system from the touch of a button or knob.

Nicolet Amplifiers (AT2 and AT2 + 6):
The Nicolet amplifiers are DC powered electrical devices that record, amplify and transmit responses from the nerve and/or muscle to the Nicolet EDX console base. The AT2 amplifier collects up to two channels of neurophysiological information and the AT2 + 6 amplifier collects up to 8 channels of neurophysiological information.

Personal Computer (PC) with Keyboard and Mouse:
The Nicolet EDX system hardware is used in conjunction with a personal computer (PC), which is offered in either a desktop or laptop configuration. The Viking software is supplied preloaded onto the PC.

Display Monitor:
The desktop PC version requires a display monitor which is provided with the Nicolet EDX system hardware. The laptop version does not require a separate display monitor beyond the built-in laptop display; however, an external display monitor may be used if desired. The additional display monitor is facilitated through the connection to an isolation transformer that is included with a desktop PC and available as an optional accessory for laptop based systems.

Description of Optional Accessory Components

HB6 and HB7 Head Boxes:
The HB6 and HB7 Head Boxes are passive devices. They can be connected to the AT2+6 Amplifier via a cable to allow the electrodes' receptacles to be in closer proximity to the patient.

Electrical Stimulator Probes:
There are three types of electrical stimulator probes available for use with the Nicolet EDX System Hardware: (1) the WR 50 comfort Plus Probe, (2) the RS 10 Comfort Probe and (3) the S403 Probe. The probes connect to the Nicole EDX console base via a cable. Each probe contains a tip that facilitates direct stimulus contact to the patient when activated. The probes can deliver a stimulus ranging from 0 – 400 V / 0 - 100 mA.

SP-1/SP-2 Electrical Stimulus Switching Units:
The SP-1 and SP-2 Stimulus Switching Units allow the user to connect multiple sets of electrodes on the patient for stimulation at different locations.

Footswitch and Triple Footswitch:
The footswitches allow the user to activate defined functions such as electrical stimulation and initiate acquisition of trace data. Pressing the footswitch activates or deactivates the user defined function.

Patient Response Button:
The patient response button allows the patient to respond to a rare stimulus during specific EP testing. The patient presses the button when the rare stimulus is detected. The Nicolet EDX senses the button press and increments a count.

Visual Stimulators:
(1) LED goggles are available to provide visual stimulation to the patient when the Visual Evoked Potential (VEP) software option is in use.

(2) A photic strobe is also a visual stimulus option. It can be mounted on an optional stand Similar to the other visual stimulus; it is used with the VEP option. All three visual

stimulators have no controls or indicators and are connected to the Nicolet EDX Console Base Unit. This photic strobe was previously cleared under K921927 and K991054.

Headphones or other Auditory Transducers:
Headphones are available, or other auditory transducers may be used to provide auditory stimulation to the patient through the transducer when the Auditory Evoked Potential (AEP) is in use. Headphones and transducers have no controls or indicators and are connected to the Nicolet EDX Console Base unit auditory stimulator output connectors.

Cart and Printer:
The metal cart provides a convenient way to contain all of the components of the Nicolet EDX System Hardware into one mobile location. The cart has lockable wheels and a convenient handle to facilitate movement of the cart. Two articulating arms are provided for mounting the display monitor and amplifier. There are multiple shelves present to accommodate the placement and storage of various Nicolet EDX System Hardware components and supplies. A retractable keyboard shelf and mouse pad is available. In terms of printing capabilities, a printer equivalent to a DeskJet or Laser printer is available for connection to the system to print reports or screen copies.

5. Indications for Use:

The CareFusion Nicolet EDX is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiological information from the human nervous and muscular systems including Nerve Conduction (NCS), Electromyography (EMG), Evoked Potentials (EP), Autonomic Responses and Intra-Operative Monitoring including Electroencephalography (EEG).

Evoked Potential (EP) includes Visual Evoked Potentials (VEP), Auditory Evoked Potentials (AEP), Somatosensory Evoked Potentials (SEP), Electroretinography (ERG), Electrooculography (EOG), P300, Motor Evoked Potentials (MEP). The Nicolet EDX with Viking Software may be used to determine autonomic responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response and Sympathetic Skin Response). Autonomic testing also includes assessment of RR Interval variability. The Nicolet EDX with Viking Software is used to detect the physiologic function of the nervous system, for the location of neural structures during surgery, and to support the diagnosis of neuromuscular disease or condition.

The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the nerve; Electromyography measures the electrical activity of the muscle and Evoked Potentials measure electrical activity from the Central Nervous System.

The Nicolet EDX with Viking Software is intended to be used by a qualified healthcare provider.

6 Summary of Technical Characteristics Compared to the Predicate Devices

The CareFusion Nicolet EDX System with Viking Software is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristic to its predicate devices through comparison in areas that include intended use,

design, functionality, principle of operation, specifications, material composition and performance.

1. General

Characteristic	CareFusion 209, Inc. Nicolet EDX System (This Submission)	CareFusion 209, Inc. Nicolet Viking II (K890495)	Oxford Instruments Medical Systems (now owned by CareFusion), Millennium (now called Synergy Mobile) System (K965065)	Oxford Instruments Medical Systems (now owned by CareFusion), Synergy IOM System (K984052)	CareFusion 209, Inc. Bravo Multi-Modality System (K991054)	TeleEMG, LLC Focus EMG (K102610)	Cadwell Cascade, Cascade Elite, Cascade Pro (K924723)	Nihon Koden Micro, Neuropack, Neuropack S1 (K010590)
1.1 Indications for Use	The CareFusion Nicolet EDX is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiological information from the human nervous and muscular systems including Nerve Conduction (NCS), Electromyography (EMG), Evoked Potentials (EP), Autonomic Responses and Intra-Operative Monitoring including Electroencephalography (EEG). Evoked Potential (EP) includes Visual Evoked Potentials (VEP), Auditory Evoked Potentials (AEP), Somatosensory Evoked Potentials (SEP), Electroretinography	The Nicolet Viking II is for data acquisition, display, analysis, reporting, and management of electrophysiological information from the human nervous and muscular system in order to detect changes in the functional state of the nervous system, or for the location of neural structures during surgery. (The Nicolet Viking II 510(k) submission did not explicitly call out an Intended Use statement. The device is used for the intended use noted here.)	The Millennium is a 2 or 5 channel electromyograph which provides fac1lities for EMG and Evoked Potentials testing for a range of clinical applications. Millennium is designed to enable reliable recording, display and documentation of electrophysiological information from the human nervous and muscular system in a clinical environment.	The Synergy 10M system is a 2, 5, or 10 channel electromyograph which provides facilities for EMG, EEG, Evoked Potentials, ECG and NCV testing to be used for Intra-Operative Monitoring. Synergy 10M is designed to provide data recording, display and reporting of electrophysiological information from the human nervous and muscular system in order to detect changes in the functional state of the nervous system, or for the location of neural structures. Additional features are provided within the 10M system to allow manual repetitive sequences to be automated, and	The Bravo Multi-Modality System is intended to record and display EEG, EP, EMG and TCD data in the clinic and hospital (including the hospital room, operating room, emergency room, intensive care unit, neuro intensive care unit, critical care unit, etc.), and to import and display data from third-party monitoring devices. It is intended to aid the diagnosis and monitoring of potential disorders of the central and peripheral nervous system and muscles. It differs from the predicate devices in that it contains multiple modalities in a single device, whereas each predicate device has a	The Focus is intended for use by a healthcare provider to perform nerve conductions and EMG studies as an aid in the evaluation of patients with diseases of muscle and nerves. The machine can also use electrical stimulus or sound stimulus for evoked potentials (EP) studies.	Indications for Use include the following: 1, evaluation of nerve, spinal cord, and cortical functionality and integrity; 2, electro-neural measurements requiring multiple concurrent stimulators of different types; 3, measurement of sensory and motor conduction latencies, including those of the peripheral nerves, spinal cord and central nervous system; 4, measurement of evoked potential amplitudes and latencies generated by the electrical, auditory	The MEB-9100A Series Neuropack Evoked Potential and EMG Measuring System is intended to monitor, record and display the bioelectric signals produced by muscles, to stimulate peripheral nerves, and to monitor, record and display the electrical activity produced by nerves to aid the clinician in the diagnosis and prognosis of neuromuscular disease (EMG). The device is also intended to measure and display nerve conduction time by applying a stimulus to a patient's nerve (NCV). The device is not intended for transcranial stimulation for motor conduction studies. The device may use electrical stimulus, visual stimulus, or sound stimulus for use in evoked response measurements (EP). The device may be used to

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	(ERG), Electrooculography (EOG), P300, Motor Evoked Potentials (MEP). The Nicolet EDX with Viking Software may be used to determine autonomic responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response and Sympathetic Skin Response). Autonomic testing also includes assessment of RR Interval variability. The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the nerve; Electromyography measures the electrical activity of the muscle and Evoked Potentials measure electrical activity from the Central			to provide automatic warnings when neurological parameters exceed user defined limits.	very limited number of modalities. Nevertheless, like the predicate devices, the Bravo Multi-Modality System is intended to involve competent human intervention before any impact on human health occurs (i.e., clinical judgment and experience must be used to check and interpret the system's output).		and visual stimulators provided with the Cascade; 5, localization of nerves, nerve roots, and other neutrally active tissue by observing the response of muscle, nerve, spinal cord or brain to electrical or mechanical stimulation of the tissue; 6, use of anesthetic patients; 7, Assessment of myoneural junction blockade.	determine autonomic responses as psychological indicators by measuring the electrical resistance of the skin and the tissue path between two electrodes applied to the skin. The device may also measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head (EEG). The device is intended for use by medical personnel within a medical facility or outside of a medical facility under direct supervision of a medical professional. The device may also be placed in the intensive care unit or operating room for continuous recording. The device is available for use on any patient as determined by the medical professional including adults and children.

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	Nervous System. The Nicolet EDX with Viking Software is intended to be used by a qualified healthcare provider.							
1.2 Warnings	Items related to off-label use or misuse.	Items related to off-label use or misuse.	Items related to off-label use or misuse.	Items related to off-label use or misuse.	Items related to off-label use or misuse.	Items related to off-label use.	Items related to off-label use.	Items related to off-label use.
1.3 Contra-indications	Items related to design and indicated use limitations, such as, not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment	Items related to design and indicated use limitations, such as, not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment.	Items related to design and indicated use limitations, such as, not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment	Items related to design and indicated use limitations, such as, not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment	Items related to design and indicated use limitations, such as, not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment	Items related to design and indicated use limitations, such as, not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment	Items related to design and indicated use limitations, such as, not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment	Unknown

2. General

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2.1 General systems approach	Computer based equipment with dedicated hardware peripherals / components.	Computer based equipment with dedicated hardware peripherals / components.	Computer based equipment with dedicated hardware peripherals / components.	Computer based equipment with dedicated hardware peripherals / components.	Computer based equipment with dedicated hardware peripherals / components.	Computer based equipment with dedicated hardware peripherals / components.	Computer based equipment with dedicated hardware peripherals / components.	Computer based equipment with dedicated hardware peripherals / components.
2.2 User input device	Window mouse/keyboard driven graphic interface with dedicated control panel.	Window mouse/keyboard driven graphic interface with dedicated control panel.	Window mouse/keyboard driven graphic interface with dedicated control panel.	Window mouse/keyboard driven graphic interface with dedicated control panel.	Window mouse/keyboard driven graphic interface with dedicated control panel.	Window mouse/keyboard driven graphic interface with built-in keyboard.	Window mouse/keyboard driven graphic interface with dedicated control panel.	Window mouse/keyboard driven graphic interface with dedicated control panel.
2.3 User output device	Digital color display and commercial printers	Digital color display and commercial printers	Digital color display and commercial printers	Digital color display and commercial printers	Digital color display and commercial printers	Digital color display and commercial printers	Digital color display and commercial printers	Digital color display and commercial printers
2.4 Patient inputs	2 to 8 channel amplifier, isolated	2 to 8 channel amplifier, isolated	2 to 10 channel amplifier, isolated	2 to 10 channel amplifier, isolated	2 to 10 channel amplifier, isolated	2 channel amplifier, isolated	2 to 10 channel amplifier, isolated	2 to 4 channel amplifier, isolated; newer version up to 16 channels
2.5 Signal acquisition	Analog to digital conversion at 48kHz sample rate	Analog to digital conversion at 48kHz sample rate	Analog to digital conversion at variable sample rate	Analog to digital conversion at variable sample rate	Analog to digital conversion at variable sample rate	Analog to digital conversion at variable sample rate	Analog to digital conversion at variable sample rate	Analog to digital conversion, unknown rate
2.6 Trigger input (synchronization to external events)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2.7 Trigger output (synchronization for external devices)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

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2.8 Footswitch for hands-free operation	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2.9 Use of standard software platform (Operating System)	Yes Microsoft Windows	Yes Intel iRMX	Yes Microsoft Windows	Yes Microsoft Windows	Yes Microsoft Windows	Yes Microsoft Windows	Yes Microsoft Windows	Yes Microsoft Windows
2.10 Customization of protocols	Via storage / retrieval of user defined settings	Via storage / retrieval of user defined settings	Via storage / retrieval of user defined settings	Via storage / retrieval of user defined settings	Via storage / retrieval of user defined settings	Via storage / retrieval of user defined settings	Via storage / retrieval of user defined settings	Via storage / retrieval of user defined settings
2.11 Application flexibility / expandability	Via software update	Via software update	Via software update	Via software update	Via software update	Via software update	Via software update	Via software update
2.12 Safety Standards	EN/IEC 60601-1:1998 + A1:1991+A2:1995, IEC 60601-1-1:2000 EN/IEC 60601-1-2: Ed. 2.0+A1:2004 IEC 60601-2-40: 1998, Ed:1, UL 60601-1: 2003-04-25 ED1 Rev:2003/06/30, CAN/CSA-C22.2 no. 601.1-M90 Issue:1990/01/01 Rev:2003/11	UL 544, IEC 60601-1, IEC 60606-1-2, CSA-C22.2 No 125-M1984	IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-2-40, European Community (CE Mark)	IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-2-40, European Community (CE Mark)	IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-2-26, IEC 60601-2-40, European Community (CE Mark)	IEC 60601-1-1:2000, IEC 60601-1-2:2001, IEC 60601-1-2-40:1998, IEC 62471:2006	UL 2601-1 CSA601-1	IEC 60601-1 (1988-12), Amendment 1 (1991-11), Amendment 2 (1995-03); IEC 60601-1-1 (1992-06), Amendment 1 (1995-10); EN 60601-1-2 (1993-05), IEC 60601-2-40 (1998)

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	European Community (CE Mark)							
2.13 Patient circuitry isolation	Optic/transformer	Optic/transformer	Optic/transformer	Optic/transformer	Optic/transformer	Optic/transformer	Optic/transformer	Optic/transformer
2.14 System components	EDX base console including 2 electrical stimulators, auditory stimulator, trigger input/output, LED goggle interface; Control panel; Amplifier; Computer, monitor, keyboard, mouse, printer	Base unit including 2 electrical stimulators, auditory stimulator, trigger input/output, LED goggle interface; Control panel; Amplifier; Computer, monitor, keyboard, mouse, printer	base unit including 2 electrical stimulators, auditory stimulator, trigger input/output, LED goggle interface; Control panel; Amplifier; Computer, monitor, keyboard, mouse, printer	base unit including 2 electrical stimulators, auditory stimulator, trigger input/output, LED goggle interface; Control panel; Amplifier; Computer, monitor, keyboard, mouse, printer	base unit including 2 electrical stimulators, auditory stimulator, trigger input/output, LED goggle interface; Control panel; Amplifier; Computer, monitor, keyboard, mouse, printer	Focus EMG device; USB cable; Footswitch; Electrical Stimulator; Notebook PC based system	base unit including 2 electrical stimulators, auditory stimulator, trigger input/output, LED goggle interface; Control panel; Amplifier; Computer, monitor, keyboard, mouse, printer	base unit including 2 electrical stimulators, auditory stimulator, trigger input/output, LED goggle interface; Control panel; Amplifier; Computer, monitor, keyboard, mouse, printer
2.15 System – computer interface	USB	Proprietary	USB	USB	Proprietary	USB	USB	USB
2.16 System power supply	Mains (100 – 240 VAC) thru an isolation transformer	Mains (110 – 240 VAC) thru an isolation transformer	Mains (110 – 240 VAC) thru an isolation transformer	Mains (110 – 240 VAC) thru an isolation transformer	Mains (110 – 240 VAC) thru an isolation transformer	Electronic unit: 5VDS System with personal computer: 100 – 120/200-24- VAC	Mains (110 – 240 VAC) thru an isolation transformer	Mains (110 – 240 VAC) thru an isolation transformer
2.17 Amplifier power supply	15 VDC from base console	15 VDC from base unit	15 VDC from base unit	15 VDC from base unit	15 VDC from base unit	USB	DC from base unit	DC from base unit
2.18 Size (L/W/D) cm	35.6 x 34.3 x 8.6 (base console)	114 x 61 x 81 (includes cart)	50 x 20.9 x 32.1 (base unit)	50 x 20.9 x 32.1 (base unit)	114 x 61 x 81 (includes cart)	9 x 27 x 5 (base unit)	5 x 30 x 28	Unknown
2.19 Weight kg	3.5 (base console)	73 (includes cart)	7.1 (base unit)	7.1 (base unit)	73 (includes cart)	3.5	2 (base unit)	Unknown

3. Design - Acquisition

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3.1 Number of channels	2 to 8	2 to 8	2 to 10	2 to 10	2 to 16	2	2 to 32	2 to 16
3.2 CMMR	> 110 dB	> 105 dB	> 110 dB	> 110 dB	> 105 dB	> 100 dB	> 95 dB	> 112 dB
3.3 Noise	< 0.6uV RMS (from 2 Hz to 10 kHz)	< 0.7uV RMS (from 2 Hz to 10 kHz)	< 0.7uV RMS (from 0.1 Hz to 10 kHz)	< 0.7uV RMS (from 0.1 Hz to 10 kHz)	< 0.7uV RMS (from 2 Hz to 10 kHz)	< 0.6 uV RMS	< 4uV peak to peak (from 10 Hz to 3 kHz)	< 0.6 uV
3.4 Input impedance	>1000 MΩ	>1000 MΩ	>1000 MΩ	>1000 MΩ	>1000 MΩ	> 100 MΩ	> 100 MΩ	> 1000 MΩ
3.5 Low Filter	0.05 Hz to 5 kHz	0.2 Hz to 5 kHz	0.1 Hz to 2 kHz	0.1 Hz to 2 kHz	0.1 Hz to 5 kHz	0.05 Hz to 3 kHz	0.5 Hz to 100 Hz	Unknown
3.6 High filter	30 Hz to 20 kHz	30 Hz to 20 kHz	30 Hz to 20 kHz	30 Hz to 20 kHz	10 Hz to 10 kHz	10 Hz to 10 kHz	30 Hz to 5 kHz	Unknown
3.7 Notch filter	50 / 60 selectable	50 / 60 selectable	50 / 60 selectable	50 / 60 selectable	50 / 60 selectable	50 / 60 selectable	50 / 60 selectable	50 / 60 selectable
3.8 A/D conversion	24 bit	16 bit	16 bit	16 bit	16 bit	16 bit	16 bit	16 bit
3.9 Sampling rate (cumulative)	384 kHz	100 kHz	250 kHz	250 kHz	100 kHz	200 to 8 kHz	200 kHz	Unknown
3.10 Time base range	0.01 to 5000 ms	0.01 to 5000 ms	0.01 to 5000 ms	0.01 to 5000 ms	0.01 to 5000 ms	2 to 5000 ms	1 to 1000 ms	Unknown
3.11 Number of Time bases allowed	Multiple	Multiple	Multiple	Multiple	Multiple	Single	Multiple	Single
3.12 Trigger mode	Free run, internal, external	Free run, internal, external	Free run, internal, external	Free run, internal, external	Free run, internal, external	Free run, internal, external	Free run, internal, external	Free run, internal, external
3.13 Signal delay (pre/post)	-3000 to +500 ms	-3000 to +500 ms	-3000 to +500 ms	-3000 to +500 ms	-3000 to +500 ms	-10000ms to +10000ms	Unknown	Unknown
3.14 Impedance meter	500 Ω to 480 kΩ	500 Ω to 500 kΩ	500 Ω to 500 kΩ	500 Ω to 500 kΩ	500 Ω to 500 kΩ	0 to 100 kΩ	Yes value unknown	Yes value unknown

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4.1 Electrical Stimulator								
4.1.1 Type	Constant Current or Constant Voltage	Constant Current or Constant Voltage	Constant Current or Constant Voltage	Constant Current or Constant Voltage	Constant Current or Constant Voltage	Constant Current	Constant Current	Constant Current
4.1.2 Number	1 or 2	1 or 2	1 or 2	1 or 2	1 or 2	1	2	2
4.1.3 Maximum Output	100mA or 400V	100mA or 400V	100mA or 300V	100mA or 300V	100mA or 400V	100mA	100mA	Unknown
4.1.4 Duration	0.01 to 1 ms	0.01 to 1 ms	0.05 to 1 ms	0.05 to 1 ms	0.01 to 1 ms	0.1 to 5 ms	0.05 to 1 ms	Unknown
4.1.5 Mode	Single or Train	Single or Train	Single or Train	Single or Train	Single or Train	Single or Train	Single or Train	Single or Train
4.1.6 Biphasic	Yes	No	Yes	Yes	No	No	No	Unknown
4.2 Auditory Stimulator								
4.2.1 Type	Click, Pip, Burst	Click, Pip, Burst	Click, Pip, Burst	Click, Pip, Burst	Click, Pip, Burst	Click, Pip, Burst	Click	Click, Pip, Burst
4.2.2 Intensity	0 to 139 dB pSPL	0 to 139 dB pSPL	0 to 139 dB pSPL	0 to 139 dB pSPL	0 to 139 dB pSPL	0 to 126 dB pSPL	0 to 105 dB pSPL	Unknown
4.2.3 Polarity	Condensation, Rarefaction, Alternating	Condensation, Rarefaction, Alternating	Condensation, Rarefaction, Alternating	Condensation, Rarefaction, Alternating	Condensation, Rarefaction, Alternating	Condensation, Rarefaction, Alternating	Condensation, Rarefaction, Alternating	Unknown
4.2.4 Tone Frequency	250 to 8000 Hz	250 to 8000 Hz	125 to 8000 Hz	125 to 8000 Hz	250 to 8000 Hz	100 to 8000 Hz	No	Unknown
4.2.5 Click Duration	0.05 to 1 ms	0.1 ms	0.05 to 1 ms	0.05 to 1 ms	0.05 to 0.5 ms	0.1 to 5 ms	0.1 ms	Unknown
4.2.6 Side	Left, Right, Both	Left, Right, Both	Left, Right, Both	Left, Right, Both	Left, Right, Both	Left, Right, Both	Left, Right, Both	Left, Right, Both
4.2.7 Transducers	TDH 39, TIP 300, Bone Vibrator	TDH 39, TIP 300, Bone Vibrator	TDH, TIP, Bone Vibrator	TDH, TIP, Bone Vibrator	TDH 39, TIP 300, Bone Vibrator	TDH 39	TDH 39	TDH, TIP

5. EMG Application Modules

Characteristic	CareFusion 209, Inc. Nicolet EDX System (this submission)	CareFusion 209, Inc. Nicolet Viking II (K890495)	Oxford Instruments Medical Systems (now owned by CareFusion), Millennium (now called Synergy Mobile) System (K965065)	Oxford Instruments Medical Systems (now owned by CareFusion), Millennium (now called Synergy Mobile) System (K984052)	CareFusion 209, Inc. Bravo Multi-Modality System (K991054)	TeleEMG, LLC Focus EMG (K102610)	Cadwell Cascade. Cascade Elite, Cascade Pro (K924723)	Nihon Koden Micro, Neuropack, Neuropack S1 (K010590)
5.1 Free Run Acquisition	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5.2 Nerve Conduction Study (NCS)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5.3 Stimulator Triggered	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5.4 Signal Triggered Acquisition	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5.5 Spontaneous Activity (SPA)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5.6 Single Fiber EMG (SFEMG)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5.7 Motor Unit Analysis	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5.8 F-Wave	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5.9 H Reflex (H-Wave)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5.10 Sympathetic Skin Response (SSR)	Yes	No	Yes	Yes	No	No	No	No

6. Evoked Potential Application Modules								
Characteristic	**CareFusion 209, Inc. Nicolet EDX System (this submission)**	**CareFusion 209, Inc. Nicolet Viking II (K890495)**	**Oxford Instruments Medical Systems (now owned by CareFusion), Millennium (now called Synergy Mobile) System (K965065)**	**Oxford Instruments Medical Systems (now owned by CareFusion), Millennium (now called Synergy Mobile) System (K984052)**	**CareFusion 209, Inc. Bravo Multi-Modality System (K991054)**	**TeleEMG, LLC Focus EMG (K102610)**	**Cadwell Cascade. Cascade Elite, Cascade Pro (K924723)**	**Nihon Koden Micro, Neuropack, Neuropack S1 (K010590)**
6.1 Somatosensory EP (SEP)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
6.2 Auditory EP (AEP)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
6.3 Visual EP (VEP)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
6.4 P300	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
6.5 LED Goggles/Photic (Visual EP Flash)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

7. MMP Application Modules								
Characteristic	**CareFusion 209, Inc. Nicolet EDX System (this submission)**	**CareFusion 209, Inc. Nicolet Viking II (K890495)**	**Oxford Instruments Medical Systems (now owned by CareFusion), Millennium (now called Synergy Mobile) System (K965065)**	**Oxford Instruments Medical Systems (now owned by CareFusion), Millennium (now called Synergy Mobile) System (K984052)**	**CareFusion 209, Inc. Bravo Multi-Modality System (K991054)**	**TeleEMG, LLC Focus EMG (K102610)**	**Cadwell Cascade. Cascade Elite, Cascade Pro (K924723)**	**Nihon Koden Micro, Neuropack, Neuropack S1 (K010590)**
7.1 Free Run Acquisition	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
7.2 Triggered Acquisition	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
7.3 Trigger Input/Output	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
7.4 Electrical Stimulator	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
7.5 Auditory Stimulator	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
7.6 Visual Stimulator	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
7.7 SSR	Yes	No	Yes	Yes	No	No	No	No
7.8 RR Interval	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes

8. IOM Application Modules								
Characteristic	**CareFusion 209, Inc. Nicolet EDX System (this submission)**	**CareFusion 209, Inc. Nicolet Viking II (K890495)**	**Oxford Instruments Medical Systems (now owned by CareFusion), Millennium (now called Synergy Mobile) System (K965065)**	**Oxford Instruments Medical Systems (now owned by CareFusion), Millennium (now called Synergy Mobile) System (K984052)**	**CareFusion 209, Inc. Bravo Multi-Modality System (K991054)**	**TeleEMG, LLC Focus EMG (K102610)**	**Cadwell Cascade. Cascade Elite, Cascade Pro (K924723)**	**Nihon Koden Micro, Neuropack, Neuropack S1 (K010590)**
8.1 IOM	Yes	No	No	Yes	Yes	No	Yes	Yes
8.2 Processed EEG	Yes	No	No	No	Yes	No	Yes	Yes
8.3 MEP	Yes	No	No	Yes	Yes	No	Yes	Yes

7 Summary of Non-Clinical Performance Testing Conducted for the Determination of Substantial Equivalence

Biocompatibility:

CareFusion has demonstrated the biocompatibility of all direct and indirect patient contacting material associated with the CareFusion Nicolet EDX (Viking EDX) through compliance with ISO 10993-1: 2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. Test results have indicated that contacting materials complies with the standard and are safe for its intended use.

Software testing:

The Viking EDX contains MODERATE level of concern software. The software was designed and developed according to a robust software development process, and was rigorously verified and validated consistent with the following guidelines:

- FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05;
- FDA guidance: Off-the-shelf software use in medical devices, 09 Sep 99; and
- FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.

The tests results demonstrated that the Viking EDX complies with its predetermined specifications.

Electrical Safety and Electromagnetic Compatibility (EMC) Testing:

The Viking EDX was tested for electrical safety. Test results demonstrated that the Viking EDX complies with the following standards:

- IEC 60601-1: 1988, Am1: 1991, Am2: 1995, Medical Electrical Equipment, Part 1: General Requirements for Safety; and
- UL 60601-1: 2006, Medical Electrical Equipment, Part 1: Particular Requirements for Safety.

Electromagnetic Compatibility (EMC) testing was conducted on the Viking EDX according to the applicable standard. Test results indicated that the system complies with the following:

- IEC 60601-1-2: 2001, Am1: 2004, Medical Electrical Equipment, Part 1: Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

Performance Testing – Bench:

The Viking EDX was tested to assess performance in accordance with requirements of the applicable performance standard. Test results demonstrated that the Viking EDX met specifications and complies with the following standard:

- IEC 60601-2-40: 1998, Medical Electrical Equipment, Part 2-40: Particular Requirements for the Safety of Electromyographs and Evoked Response Equipment.

Performance Testing – Animal & Clinical:
Animal testing and clinical testing were not needed to demonstrate safety and effectiveness.

8 Conclusion

The technological characteristics and performance data for the CareFusion Nicolet EDX System with Viking Software demonstrates that it is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 15 2012

Carefusion 209, Inc.
c/o Mr. Curtis T. Truesdale
Manager, Regulatory Assurance
1850 Deming Way
Middleton, WI 53562

Re: K112052
Trade/Device Name: Carefusion Nicolet EDX
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF, IKN, JXE, OLT, GWJ, GWE, GZP
Dated: February 9, 2012
Received: February 10, 2012

Dear Mr. Truesdale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K112052

Device Name: CareFusion Nicolet EDX with Viking Software

Indications for Use:

The CareFusion Nicolet EDX is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiological information from the human nervous and muscular systems including Nerve Conduction (NCS), Electromyography (EMG), Evoked Potentials (EP), Autonomic Responses and Intra-Operative Monitoring including Electroencephalography (EEG).

Evoked Potential (EP) includes Visual Evoked Potentials (VEP), Auditory Evoked Potentials (AEP), Somatosensory Evoked Potentials (SEP), Electroretinography (ERG), Electrooculography (EOG), P300, Motor Evoked Potentials (MEP). The Nicolet EDX with Viking Software may be used to determine autonomic responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response and Sympathetic Skin Response). Autonomic testing also includes assessment of RR Interval variability. The Nicolet EDX with Viking Software is used to detect the physiologic function of the nervous system, for the location of neural structures during surgery, and to support the diagnosis of neuromuscular disease or condition.

The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the nerve; Electromyography measures the electrical activity of the muscle and Evoked Potentials measure electrical activity from the Central Nervous System.

The Nicolet EDX with Viking Software is intended to be used by a qualified healthcare provider.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Kristen Bowsher

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K112052